

## **II. Remarks**

### **A. Introduction**

Reconsideration and allowance of the present application are respectfully requested.

Claims 1-5, 10-12, 16-23, 25, 26, 28, and 30-44 are pending in the present application.

Claims 1, 25, 30 and 39 are independent. Claims 25 and 28 are amended. Claims 39-44 are new. No new matter has been introduced.

### **B. Claim Rejections under 35 U.S.C. § 112**

#### **1. Enablement**

Claims 1-5, 10-12, 16-23, 25, 26, 28, 30-39 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for “providing no guidance as to adhesives which may be utilized nor to what type of adhesives may or may not be transparent or translucent.” (See Office Action, page 7). It is widely accepted that an application “need not teach, and preferably omits, what is well known in the art.” *See In re Buchner*, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Transparent or translucent adhesives are widely known by persons of ordinary skill in the art. For example, U.S. Patent No. 5,553,605 identifies several transparent adhesives. (*See* Col. 3, lines 50-55). Also, the Office Action identifies a transparent adhesive. (*See* Office Action, page 5). Further, the specification on page 32 identifies Llummar films having an adhesive layer that is clear. Thus, the specification satisfies the enablement requirement and teaches a person of ordinary skill how to make and use the claimed invention.

#### **2. Indefiniteness**

Claims 1-5, 10-12, 16-23, 25, 26, 28, 30-39 stand rejected under 35 U.S.C. § 112, second paragraph, for being indefinite. The Office Action states “Applicant’s recite a product comprising a first adhesive layer and a second backing layer, said backing layer transparent so that the skin may be seen through the device.” (*See* Office Action, page 8). Claim 1 recites a “patch applied to skin for reducing exposure to ultraviolet (UV) radiation, comprising: a first layer that is adhesive; and a second layer adjacent to the first layer comprising a material; and one or more UV radiation blocking agents; wherein the second layer is transparent such that the skin is visible through the patch.” The standard for determining definiteness of a claim is based on whether a person of ordinary skill would understand with a reasonable degree of clarity. *See* MPEP § 2173.02 (should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression

and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.”). Therefore, this rejection should be withdrawn as improper.

**C. Claim Rejections under 35 U.S.C. § 103(a)**

**1. Combination of Jenkins, Edwards and Woods is Improper.**

Independent Claims 1, 25, and 30, as well as dependent Claims 2-5, 10-12, 18-20, 22, 23, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of U.S. Patent No. 5,352,457 to Jenkins, et al. (“Jenkins”) in view of U.S. Patent No. 6,037,280 to Edwards et al. (“Edwards”), WO02/059407 to Woods et al. (“Woods”) and U.S. Patent No. 5,609,945 to von Trebra et al. (“von Trebra”). Applicant traverses this rejection in view of the arguments set forth below.

To reject a claim under Section 103(a), the Patent Office must establish a *prima facie* case of obviousness that requires “consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991); see also *Dystar Textilfarben GmbH & Co. Deutschland Kg v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). It is improper to merely identify elements in various cited references, because doing so “would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.” *See In re Rouffet*, 149 F.3d 1350, 1357-58 (Fed. Cir. 1998); *See Dennison Manufacturing Company v. Panduit Corp.*, 475 US 809, 229 USPQ 478, 479 (1986) (one “must not pick and choose isolated elements from the prior art and combine them so as to yield the invention in question if such a combination would not have been obvious at the time of the invention.”). “It is impermissible to use the claimed invention as an instruction manual or ‘template’ to piece together the teachings of the prior art so that the claimed invention is rendered obvious.” *See In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). Picking and choosing among selected teachings in the prior art is a form of improper hindsight reconstruction. *See In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

The Office Action alleges that Jenkins teaches a transdermal device having a backing layer, which may be a metallized polyester film, adjacent to an adhesive layer. (*See Office*

Action, page 3). The Office Action uses von Trebra to allegedly teach a metallized polyester film having 20% visible light transmission to demonstrate that the metallized polyester film of Jenkins is also transparent. The Office Action admits that Jenkins fails to teach the use of UV blocking agents as claimed, and turns to Edwards and Woods to allegedly remedy the deficiency of Jenkins. (See Office Action, page 4). The Office Action also states, incorrectly and in direct contradiction to other statements in the Office Action, that “Jenkins teaches the patch as claimed with the addition of UV blocking agents.” (See Office Action, page 4). This statement should be withdrawn because it is without support.

The combination of Jenkins with Edwards and Woods is improper because the Office Action has picked and chosen among different references various features and used improper hindsight to rearrange the references to arrive at the claimed invention. Jenkins teaches a transdermal device that has at least three layers, backing layer 6, layer 4, and release paper 2. (See Jenkins, FIG. 1). Jenkins’ transdermal device delivers an active ingredient through the skin to the person wearing the transdermal device. (See Jenkins, Col. 2, lines 50-54 and Col. 1, lines 7-10). No UV blocking agents are taught in Jenkins. In contrast, Edwards and Woods are not directed to transdermal devices. Instead, these references relate to fabrics. There is absolutely nothing in Edwards or Woods that teaches that the fabrics are applied directly to the skin or contain an active ingredient. The fabrics of Edwards or Woods may be worn over the skin but are certainly not applied to the skin using an adhesive as done with the transdermal device of Jenkins. In addition, Jenkins fails to teach that fabrics of Edwards or Woods would be a suitable carrier for the active ingredient. Thus, there would be no expectation of success in combining the transdermal device of Jenkins and fabrics of Edwards or Woods. Without the requisite expectation of success, the combination uses hindsight that picks and chooses elements from each of these references in an attempt to arrive at the claimed invention. Thus, the combination of Jenkins, Edwards, and Woods is improper and should be withdrawn.

In addition, the present invention is not directed to transdermal devices and does not deliver active ingredients through the skin as taught by Jenkins.

Independent Claim 30 further recites a “method of reducing skin exposure to ultraviolet (UV) radiation” comprising the steps of providing a patch “wherein the patch includes a first layer that is adhesive and a second layer adjacent to the first layer comprising a material and one or more UV radiation blocking agents, wherein the second layer is transparent such that the skin is visible through the patch” and “applying the patch to the skin with the adhesive layer

contacting the skin.” Jenkins’ transdermal device delivers an active ingredient to the wearer and fails to teach a method of reducing skin exposure to radiation. Edwards and Woods relate to fabrics and fails to that the skin is visible through the patch and applying the patch to the skin. Instead Edwards and Woods teach fabrics worn as clothing that are neither transparent or applied to the skin. Thus, Edwards and Woods cannot remedy the deficiencies of Jenkins. Thus, Claim 30 is patentable over Edwards for this additional reason.

## 2. Muchin

Independent Claims 1, 25, 30, and 39, as well as dependent Claims 4, 5, 11, 12, 16-20, 22, 23, 28 and 31-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,241,998 to Muchin (hereinafter “Muchin”) for the reasons set forth in the Office Action. Applicant traverses the rejection based on the following arguments.

Independent Claim 1 recites a “patch applied to skin for reducing exposure to ultraviolet (UV) radiation” comprising “a second layer adjacent to the first layer comprising a material; and one or more UV radiation blocking agents.” Independent Claims 25, 30 and 39 recite similar features. The Office Action states that Muchin allegedly teaches an “adhesive layer, a transparent backing layer and a sunscreen.” (*See* Office Action, page 13). The Office Action also admits that Muchin fails to teach all “limitations are combined into a single composition.” (*See* Office Action, page 13). Contrary to what is stated in the Office Action, Muchin is not directed to a transdermal patch and instead teaches a dermatological patch for removing keratotic plugs from skin. (*See* Muchin, Col. 1, lines 4-6). In removing keratotic plugs, the patch of Muchin must be suitable for being stripped from the skin to remove the such materials from the pores and, thus, would be expected to be removed from the skin a short time after being applying. (*See* Muchin, Col. 8, lines 1-10). Thus, the addition of a UV radiation blocking agent would not be expected to reduce exposure to ultraviolet (UV) radiation due to the short period of time the patch is actually on the skin. Further, the wearer of the Muchin patch would generally use the patch in the bathroom as part of a daily hygiene routine and not outside where exposure to UV radiation would occur. Thus, there would be no expectation of using UV radiation blocking agents in a dermatological patch based on the teachings of Muchin.

Independent Claim 30 further recites a “method of reducing skin exposure to ultraviolet (UV) radiation” comprising the steps of providing a patch “wherein the patch includes a first layer that is adhesive and a second layer adjacent to the first layer comprising a material and one

or more UV radiation blocking agents, wherein the second layer is transparent such that the skin is visible through the patch” and “applying the patch to the skin with the adhesive layer contacting the skin.” Muchin teaches a patch for removing keratotic plugs and fails to teach reducing skin exposure to ultraviolet radiation as claimed.

In addition, Muchin fails to teach that the second layer adjacent to the first layer, i.e. the adhesive layer, contains one or more UV radiation blocking agents. Muchin states that the “*polymeric adhesive composition* can further contain optional ingredients which are generally incorporated into cosmetic preparations.” (See Muchin, Col. 5, lines 48-50; emphasis added). The paragraph goes on to list several additives for the polymeric adhesive composition, none of which are identified by Muchin as being present in the second layer adjacent to the first layer as taught by the claimed invention. Muchin provides a general statement that “other additives may be applied to the pad, or the polymeric adhesive composition or both” and gives examples in Col. 6, lines 20-28. (See Muchin, Col. 6, lines 13-28). The Office Action improperly cites this portion for teaching that “Muchin further teaches said uv agents on the surface of said backing layer (col. 6, lines 13-14).” (See Office Action, page 13). None of these additives for the pad, however, are UV radiation blocking agents as claimed. Thus, Muchin fails to teach a second layer adjacent to the first layer comprising one or more UV blocking agents as claimed. Therefore, Muchin cannot teach or suggest every element of Claims 1, 25, 30 and 39, and this rejection must be withdrawn.

#### **D. Claim Rejections under 35 U.S.C. § 102(b)**

Independent Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Muchin for the reasons set forth in the Office Action. Applicant respectfully traverses this rejection in view of the following remarks.

Independent Claim 1 recites a “patch applied to skin for reducing exposure to ultraviolet (UV) radiation” comprising “second layer adjacent to the first layer comprising a material; and one or more UV radiation blocking agents.” The Office Action states that Muchin allegedly teaches a “adhesive layer, a uv agent and a transparent backing layer.” (See Office Action, page 8). However, Muchin fails to teach that the second layer adjacent to the first layer, i.e. the adhesive layer, contains one or more UV radiation blocking agents. Muchin states that the “*polymeric adhesive composition* can further contain optional ingredients which are generally incorporated into cosmetic preparations.” (See Muchin, Col. 5, lines 48-50; emphasis added).

The paragraph goes on to list several additives for the polymeric adhesive composition, none of which are identified by Muchin as being present in the second layer adjacent to the first layer as taught by the claimed invention. Muchin provides a general statement that "other additives may be applied to the pad, or the polymeric adhesive composition or both" and gives examples in Col. 6, lines 20-28. (See Muchin, Col. 6, lines 13-28). None of these additives are UV radiation blocking agents as claimed. For the same reasons discussed above, Muchin fails to disclose a second layer adjacent to the first layer comprising one or more UV blocking agents as claimed. Therefore, Muchin cannot anticipate Claim 1 and this rejection must be withdrawn.

#### **E. Dependent Claims**

Dependent Claims 16 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin. Dependent Claims 21 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view of U.S. Patent No. 5,167,649 to Zook (hereinafter "Zook"). Dependent Claims 2, 3, 33-36 and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view of U.S. Publication No. 2003/0175328 to Shefer et al. Dependent Claims 10 and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view Zook. Dependent Claim 32 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Muchin in view U.S. Patent No. 6,103,275 to Seitz et al.

Dependent Claims 2-5, 10-12, 16-23, 26, 28, 31-38, and 40-44 depend from independent Claims 1, 25, 30 and 39, respectively. Accordingly, Claims 2-5, 10-12, 16-23, 26, 28, 31-38, and 40-44 incorporate the features of independent Claims 1, 25, 30 and 39, and are patentable over the cited references for at least the same reasons as independent Claims 1, 25, 30 and 39.

#### **F. Conclusion**

In view of the above remarks, it is believed that this application is in condition for allowance, and a Notice thereof is respectfully requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3536. All correspondence should continue to be directed to the below-listed address.

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